

REMARKS**Claim Rejections****Double Patenting**

The Examiner rejects claims 1-4, 6-12, and 15 under the judicially created doctrine of obviousness-type double patenting, as being unpatentable over claims 4-7 of United States Patent No. 5,869,035. Although not acceding to the Examiner's rejection, Applicants have canceled claims 1-4, 6-12, and 15, thereby rendering the Examiner's rejection moot.

35 U.S.C. § 112, First Paragraph

The Examiner rejects claims 1-16 and 18 under 35 U.S.C. § 112, first paragraph, on the grounds that:

[T]he specification, while being enabling for methods of inhibiting the growth of a solid tumor comprising the direct administration to a solid tumor of a xenogeneic retroviral producer cell line which comprises a retrovirus encoding HSV-TK alone or in combination with (1,3) galactosyltransferase, followed by the administration of gancyclovir, does not reasonably provide enablement for methods of treating tumors or methods of treating tumor comprising inducing hyperacute rejection wherein the method steps comprise the injection or infusion of any and all xenogeneic cells.

PTO Paper No. 7, page 6. Although not acceding to the Examiner's rejection, Applicants have canceled claims 1-16 and 18, thereby rendering the Examiner's rejection moot.

35 U.S.C. § 112, Second Paragraph

The Examiner rejects claims 6-8, 15, and 16 under 35 U.S.C. § 112, second paragraph, as being incomplete for omitting essential steps. Although not acceding to the Examiner's rejection, Applicants have canceled claims 6-8, 15, and 16, thereby rendering the Examiner's rejection moot.

35 U.S.C. § 102**35 U.S.C. § 102(e)**

The Examiner rejects claims 1, 3, 4, 6, 9-12, 15, and 16 under 35 U.S.C. § 102(e) as being anticipated by United States Patent No. 6,045,789 ("Culver *et al.*"). Although not acceding to the Examiner's rejection, Applicants have canceled claims 1, 3, 4, 6, 9-12, 15, and 16, thereby rendering the Examiner's rejection moot.

35 U.S.C. § 102(a)

The Examiner rejects claims 1-4, 6-12, and 15 under 35 U.S.C. § 102(a) as being anticipated by Klatzmann *et al.*, *Human Gene Ther.* 9:2585-94 (1998). Although not acceding to the Examiner's rejection, Applicants have canceled claims 1-4, 6-12, and 15, thereby rendering the Examiner's rejection moot.

35 U.S.C. § 103(a)

The Examiner rejects claims 1, 3-6, and 9-17 under 35 U.S.C. § 103(a) as being unpatentable due to obviousness in view of Culver *et al.* in view of Link *et al.*, *Human Gene Ther.* 9:115-34 (1998), and further in view of Link *et al.*, *Anticancer Res.* 18:2301-8 (1998). Although not acceding to the Examiner's rejection, Applicants have canceled claims 1, 3-6, and 9-17, thereby rendering the Examiner's rejection moot.

New Claims Added After Final Rejection

Applicants respectfully request the entrance and allowance of new claims 19-34. These claims are clearly supported by the specification and claims as originally filed.

Applicants now claim, in new claims 19-31, non-gene therapy-based methods for inhibiting the growth of a tumor in a human subject comprising delivering to the tumor one or more α (1,3) galactosyl epitope-containing cells. Such claims are based upon the discovery by

Applicants that delivery of α (1,3) galactosyl epitope-containing cells, such as those derived from mouse, to a tumor results in inhibition of the tumor, *and that such a result occurs independent of any gene therapy effects*. Applicants direct the Examiner's attention to page 18, lines 11-31, and page 27, lines 15-17, of the specification, wherein Applicants note that anti-tumor effects were achieved following introduction of murine vector producer cells containing the HSVtk gene to tumors in human subjects *despite less than 1% HSVtk gene transfer, and prior to administration to the subjects of ganciclovir*.


Applicants further claim, in new claims 32-34, non-gene therapy-based methods for inhibiting the growth of a tumor in a human subject comprising delivering to the tumor a murine cell line, and administering one or more chemotherapeutic agents following delivery to the tumor of the murine cell line. Such claims are based upon the discovery by Applicants that chemotherapeutic-resistant tumors become susceptible to chemotherapy once murine cells have been delivered to the tumors. Support for these amendments may be found throughout the specification and claims as originally filed.

Applicants note that if the current amendment is entered, then the captioned application will result in a total of four independent claims. Applicants therefore respectfully request that if the current amendment is entered, then the Commissioner is authorized to charge \$42.00 to Deposit Account No. 26-0084 to cover the cost of the additional independent claim.

CONCLUSION

Support for the amendments contained herein may be found in both the specification and claims as originally filed. Applicants respectfully submit that these amendments and remarks place the captioned application in condition for allowance.

Respectfully submitted,



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